



United States
Department of
Agriculture

Food Safety and
Inspection Service

July 2004

Fulfilling the Vision

Initiatives in Protecting Public Health



The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audio-tape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

To file a complaint of discrimination write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice or TDD). USDA is an equal opportunity provider and employer.

Table of Contents

SECTION I: Introduction1

SECTION II: Abstract3

SECTION III: Significant Food Safety Advancements5

Basing Policy on Science6

Listeria monocytogenes6

E. coli 0157:H77

Salmonella8

Bovine Spongiform Encephalopathy (BSE)8

Training9

Food Security10

Strengthening Oversight of Recalls11

Modernization of Enforcement Activities11

Strengthening State Reviews12

Best Practices for Animal Production12

International Food Safety12

Food Handler Education and Outreach12

SECTION IV: Achieving the Next Level of Food Safety17

Challenge One: Anticipating and Predicting Risk17

Challenge Two: Improving the Application of Risk into Enforcement Activities . . .18

Challenge Three: Improved Association of Outcomes to Surveillance Data20

Challenge Four: Improving Food Safety Beyond Our Borders21

SECTION V: Conclusion22

SECTION 1: Introduction

USDA's Food Safety and Inspection Service (FSIS) is a public health regulatory agency charged with ensuring that the United States' supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled. With the 2003 publication of "Enhancing Public Health: Strategies for the Future," FSIS outlined five goals it has been pursuing to improve the health status of consumers. In that document, FSIS outlined a series of new and comprehensive science-based initiatives to better understand, predict, and prevent microbiological contamination of meat, poultry, and egg products, thereby improving health outcomes for American families.

This document, titled "*Fulfilling the Vision*," evaluates the effectiveness of the implementation of these goals and examines many specific outcomes associated with the initiatives established in 2003. FSIS has also developed additional initiatives to continue in its pursuit of improving food safety. One of the improvements in food safety is the continued downward trend observed over the last year in the presence of several persistent pathogens in regulatory samples, including E. coli O157:H7, *Listeria monocytogenes* and *Salmonella*, as well as a significant reduction in foodborne illnesses.

We welcome the input of all interested parties to this document, and encourage the exchange of ideas, as we move toward identifying strategies and solutions that will further improve the safety of the food supply for all consumers, both domestically and internationally.

SECTION II: Abstract

The Food Safety and Inspection Service (FSIS) is responsible for ensuring that the commercial supply of meat, poultry, and egg products moving in interstate commerce or exported to other countries is safe, wholesome, and correctly labeled and packaged. In addition, FSIS ensures that products imported from other countries are produced by a system that is equivalent to that employed by FSIS.

FSIS is committed to improving public health through food safety. In 2002, USDA's Office of Food Safety established five core goals to improve food safety for American families. They continue to guide the Agency's actions:

- To improve the management and effectiveness of our regulatory programs,
- To ensure that policy decisions are based on science,
- To improve coordination of food safety activities with other public health agencies,
- To enhance public education, and
- To protect FSIS regulated products from intentional contamination.

Last year, FSIS outlined specific initiatives to fulfill these goals and thereby improving health outcomes for American families. These initiatives were reported in FSIS' food safety vision document, *Ensuring Public Health: a Vision for the Future*. As part of FSIS' continuing process to evolve, *Fulfilling the Vision* was prepared as a detailed plan to best utilize Agency resources and authorities to further enhance food protection systems during the coming year.

In this document, FSIS presents a list of accomplishments achieved over the past year that have enhanced the safety of our Nation's food supply. In addition to these ongoing efforts, the emergence of previously unrecognized pathogens, as well as new trends in food distribution and consumption, highlights the need for new strategies to reduce the health risks associated with pathogenic microorganisms in meat, poultry, and egg products. Through analysis and discussions with the scientific community, public health experts, and all interested parties, issues have been identified that need to be addressed to attain the next level of public health protection. A brief description of these challenges is also presented in this document. The resulting strategies should help FSIS pursue its goals and achieve its mission of reducing foodborne illness.

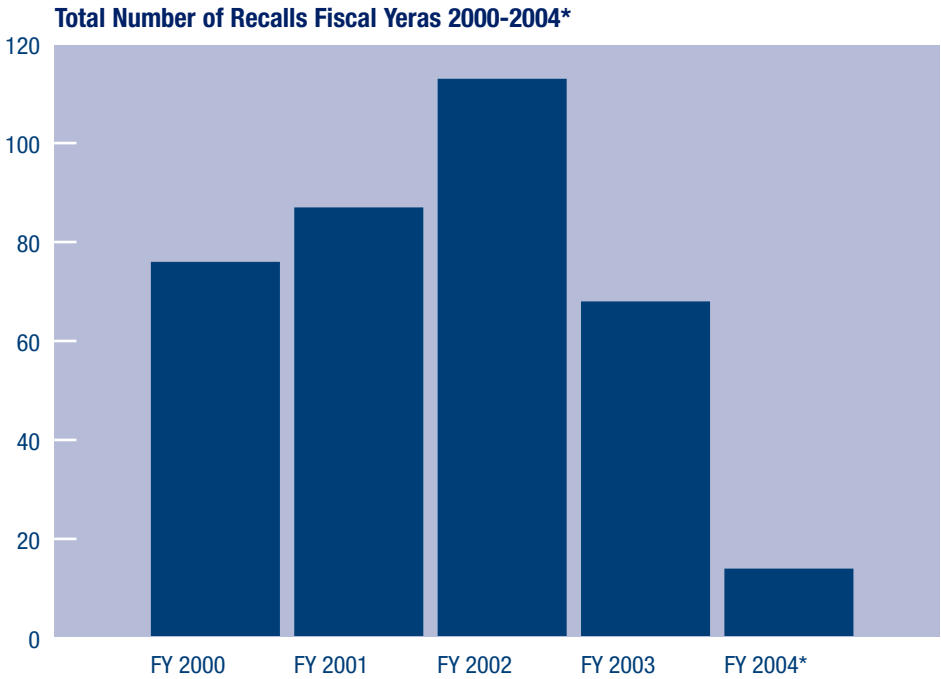
SECTION III:
Significant Food Safety
Advancements

Significant food safety advancements have been made in the past year. One of these has been improvements in implementation and verification of plant Sanitation Standard Operating Procedures (SSOP) and Hazard Analysis and Critical Control Point (HACCP) plans, leading to a dramatic decline in the number of meat and poultry product recalls during 2003. The number of Class I, or high risk, recalls in 2003 was nearly been cut in half from the total observed in 2002. In the first half of 2004, the number of Class I recalls has decreased even further to 16 at the time of this publication. This is a strong indicator that the agency's scientifically based policies and programs are working to prevent adulterated product from entering the marketplace.

Other indicators of success this past year include a trend of reduction in pathogens found in meat and poultry regulatory samples. In late 2003, FSIS released data that showed, as of September 30th, a 25-percent drop in the percentage of

positive *Listeria monocytogenes* regulatory samples from the year before, and a 70-percent decline compared with years prior to the implementation of HACCP. We are cautiously optimistic that this downward trend will continue, due to the regulation issued in June 2003 for establishments producing ready-to-eat products where *Listeria monocytogenes* is a concern. (More detail on the reduction of this and other pathogens is found in the next section of this document.)

More importantly, the accomplishments of our initiatives can be observed in the annual (2004) report on the incidence of infections from foodborne illness by the Centers for Disease Control and Prevention (CDC). The report noted significant declines from 1996 to 2003 in illnesses caused by *E. coli* O157:H7 (42%), *Salmonella* (17%), *Campylobacter* (28%), and *Yersinia* (49%). Illnesses caused by *Salmonella* Typhimurium (typically associated with meat and poultry) decreased by 38%. Between 2002



* Contains data collected through June 30, 2004

and 2003, illnesses caused by *E. coli* O157:H7, typically associated with ground beef, dropped by 36%. This reduction in *E. coli* O157:H7 illnesses brings the U.S. closer to achieving the “Healthy People 2010” goal of 1.0 case per 100,000 people.

CDC attributes the changes in the incidence of these infections to control measures implemented by government agencies and the food industry, and enhanced food safety education efforts. Specifically with regard to *E. coli* O157:H7, CDC attributes the reduction in illness caused by this pathogen to policies implemented in 2002 and 2003 by FSIS.

Basing Policies on Science

Listeria monocytogenes (Lm)

Data gathered during an outbreak of *Listeria*-related illnesses during the summer/fall of 2002, combined with other food safety investigations and in-depth verification reviews, led FSIS to conclude that some establishments were not adequately addressing the potential

for bacterial contamination in their HACCP plans, SSOP, or other control measures. As an interim measure, FSIS implemented a directive in December 2002, outlining steps to be taken by USDA inspectors to ensure that establishments producing ready-to-eat (RTE) meat and poultry products were preventing *Lm* contamination. The *Lm* directive was an aggressive and targeted approach to further reduce the risk of listeriosis from consumption of high- and medium-risk RTE products. This directive subjected establishments to intensified verification testing if they produced high- and medium- risk RTE meat and poultry products (deli meats and hot dogs) without validated controls for preventing *Lm*, or if they failed to share information related to such programs with FSIS.

In February 2003, FSIS released a draft scientific risk assessment on *Listeria* in RTE meat and poultry products. A public meeting was held on February 26, 2003, to discuss the risk assessment. The risk assessment, in conjunction with a previously released FDA/FSIS risk

ranking and public comment gathered on the topic and a peer review of the risk assessment, provided important data enabling FSIS to design a final *Lm* rule.

On June 6, 2003, FSIS issued an interim final rule requiring Federal establishments producing certain RTE meat and poultry products to take steps to reduce the incidence of *Lm*. Under the rule, establishments choose one of three approaches based upon the stringency of the control program for *Lm* that they implement. The approach taken is one factor in determining the frequency of FSIS-conducted verification activities in each establishment, with the highest frequency concentrated in establishments that rely solely on sanitation practices, compared with those that implement more aggressive and effective strategies, such as incorporating an inhibiting agent in product formulation or inserting an additional processing step to kill pathogens that may contaminate the product after cooling.

The rule became effective on October 6, 2003, and the *Lm* directive was updated to reflect the policies outlined in the rule. FSIS is accepting comments about the rule for 18 months after publication for the purpose of reviewing and evaluating the effectiveness of these approaches.

The *Listeria* rule was built upon the results of the very thorough quantitative risk assessment, which provided guidance about the practices that industry should follow in order to exert the greatest control over this pathogen in ready-to-eat meat and poultry products. The risk

assessment showed that testing the processing environment was important, in that it would help find the organism in the niches where it may reside, allowing processors to target and eliminate it from the plant environment before it could contaminate product. Most meaningfully, the risk assessment showed that an establishment could choose the most effective strategy to control *Listeria* depending on its product(s) and the environment in which it operates.

The *Listeria* rule's impact has already been significant in terms of the changes that establishments have made to prevent product from harboring this organism. FSIS recently conducted a survey of its inspection personnel in 1,400 establishments producing ready-to-eat meat and poultry products, and found that more than 87% have changed their operations in one way or another to more effectively control *Listeria monocytogenes*. More than 57% started testing for *Listeria* in the plant environment, more than 27% have initiated the use of an antimicrobial agent to inhibit the growth of this organism, and 17% started using post-lethality treatments. This rule challenged industry to do more to prevent contamination with this pathogen.

Escherichia coli O157:H7

Agency measures to prevent ground beef contaminated with *E. coli* O157:H7 from entering commerce have also yielded significant decreases in this pathogen. FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef in 1994. Over the last decade, FSIS has undertaken a number of initiatives to reduce the prevalence of

this pathogen in raw ground beef. Beginning in October 2002, FSIS required that each plant producing raw beef products reassess its HACCP plan in order to ensure product contaminated with *E. coli* O157:H7 does not enter commerce. Scientifically trained FSIS personnel then conducted the first-ever comprehensive audits of 1,500 beef establishments' HACCP plans. Sixty-two percent of those plants made major improvements based on these reassessments, and 60 percent added *E. coli* O157:H7 as a pathogen likely to occur. As a result, we are seeing a significant drop in the percentage of *E. coli* O157:H7 positive regulatory samples in ground beef.

In September 2003, FSIS released data collected from January 1 through August 31, 2003, showing a drop in the number of *E. coli* O157:H7 positive samples of ground beef that FSIS had collected, compared with past years. Of these samples, 0.32 percent tested positive for *E. coli* O157:H7, a decrease from 0.78 in 2002 and 0.84 in 2001, and 0.86 in 2000. Since 2001, FSIS has analyzed approximately 7,000 samples annually.

In addition, the agency has taken steps to begin a science-based baseline study for trimmings used to make raw ground beef, the design of which was reviewed by scientists serving on the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

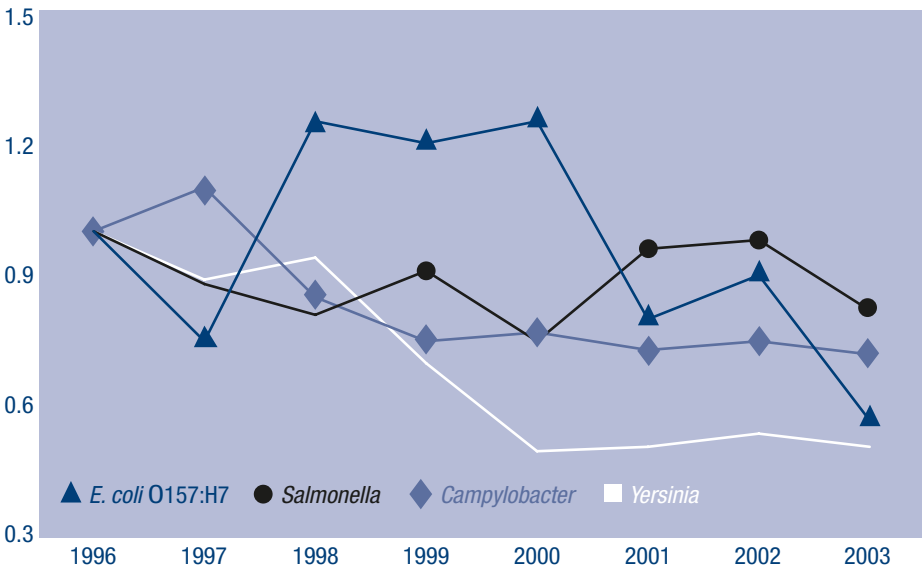
A directive was issued in May 2004 to provide new instructions to inspection program personnel for collecting samples for *E. coli*

O157:H7 testing. The directive provides new instructions for follow-up actions that FSIS personnel will take after an initial FSIS sample of raw ground beef product, raw beef patty components tests positive for *E. coli* O157:H7. It also provides new instructions to inspection program personnel for verifying the control of raw beef products that are "positive" and "presumptive positive" for *E. coli* O157:H7 and that are moved to another official establishment, landfill operation, or renderer for proper disposal.

Under the new directive, establishments that have designed and implemented sampling and verification testing and have a high degree of confidence of finding the pathogen in both trim and finished ground product will be sampled less frequently than other establishments. In addition, FSIS will weigh its sample scheduling process so that an establishment producing a large volume of raw ground beef products will be sampled more frequently than an establishment with a lower volume of production of raw ground beef products. In the future, FSIS intends to develop a random sampling and testing program for raw ground beef components and beef patty components and non-intact beef products other than ground beef, such as mechanically tenderized and injected steaks and roasts.

FSIS is considering how best to ensure that its inspectors are aware of, and have access to, the results of testing done by establishments. FSIS is considering whether some mechanism beyond discussing test results

Relative Rates of Laboratory Confirmed Cases of E. Coli O157, Campylobacter, Salmonella, and Yersinia



at the weekly meeting is necessary. FSIS' Office of Program Evaluation, Enforcement and Review (OPEER) plans to conduct an internal audit to determine the effectiveness of the new policies which have been designed to reduce the incidence of *E. coli* O157:H7.

Salmonella

A little over a year ago, FSIS also issued new procedures for utilizing *Salmonella* performance standards as a verification tool for food safety. Under these new procedures, instead of waiting for two consecutive failures of tests to trigger an in-depth review of plant SSOP and HACCP plans, reviews are initiated after any series of tests fails to meet a standard. Improvements to the in-depth review process have also been implemented, such as the inclusion of Enforcement, Investigative Analysis Officers and other HACCP-trained personnel. This process and other science based initiatives, including strategies implemented to reduce *E. coli* O157:H7, have played a significant role in reducing the prevalence of *Salmonella* in raw meat and poultry regulatory samples. Out of the number of regulatory samples collected and analyzed by FSIS between January 1 and October 31, 2003, 3.6 percent tested positive for *Salmonella*, as compared with 4.29 percent in 2002; and 10.65 percent in 1998.

Although the agency's rate of positives in regulatory samples of all three pathogens discussed may not represent the prevalence of these pathogens nationwide, it is indicative of a statistically significant downward trend.

Bovine Spongiform Encephalopathy (BSE)

The agency demonstrated its responsiveness in the immediate aftermath of the BSE discovery in Washington State in December 2003 by further strengthening existing BSE detection and prevention efforts.

Ban on Non-Ambulatory Disabled Cattle. On December 30, 2003, Secretary Ann Veneman announced a ban on all non-ambulatory disabled cattle from entering the human food supply. FSIS' Public Health Veterinarians, or PHVs, are responsible for enforcing this ban.

New Regulations Issued. Following the Secretary's immediate ban on all non-ambulatory disabled cattle, FSIS issued four Federal Register documents to further enhance safeguards to prevent BSE from entering the food supply. The regulations and policies set out in these documents add a significant level of protection to an existing strong food safety system. They also are generally consistent with those taken by Canada after the discovery of a BSE cow there in May 2003.

- **The first document was** a notice that announced that FSIS inspectors will no longer mark cattle tested for BSE as "inspected and passed" until confirmation is received that the cattle were negative for BSE. This notice was designed to prevent the entry of positive animals into the food supply.
- **In the second document, an interim final rule,** FSIS declared that skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle

30 months of age or older, and the small intestine and tonsils of all cattle are specified risk materials (SRM) and that these materials were unfit for food. These enhancements are based on conclusions drawn by the World Health Organization which state that "removal of visible nervous and lymphatic tissue from meat can provide reassurance" that BSE will not be transmitted.

- **The third document was an** interim final rule on advanced meat recovery (AMR). This rule prohibits the use of the vertebral column, skull, dorsal root ganglia, spinal cord tissue or any other SRM in AMR.
- **The fourth document was an** interim final rule that bans the practice of air-injection stunning. This was done to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of stunning cattle during the slaughter process. While the use of this type of stunning device is not common in the U.S., officially banning its use not only ensures that it will be prohibited domestically, but will also make it a requirement for equivalency in foreign establishments that export meat into the U.S.

The three interim final rules became effective on January 12, 2004. There was a significant comment period allotted for each of the final interim rules, and the agency has received approximately 22,000 comments. These are being reviewed to determine if any changes are warranted.

Participation in BSE Surveillance. The Animal and Plant Health Inspection Service (APHIS) at USDA began an enhanced animal surveillance program for BSE in June of 2004. FSIS PHVs will collaborate with APHIS by collecting brain samples from cattle that are condemned during ante-mortem inspection at federally inspected establishments. Specially trained PHVs will collect the brain samples. The samples will be shipped to the National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another USDA designated laboratory.

Training

FSIS inspectors are responsible for making the critical decisions in order to ensure the safety of meat, poultry, and egg products. Thus, it is essential to have a workforce that is well trained in the science of food safety, using modern methods in order to enhance effectiveness of training. With a workforce numbering approximately 10,000 people, training all employees is a considerable undertaking. FSIS has made a positive start in this effort and will work to train more of its workforce in the coming year.

In April 2003, FSIS inaugurated a new Food Safety Regulatory Essentials (FSRE) training program, which is designed to better equip inspection personnel in verifying an establishment's HACCP food safety system. All students receive training in the fundamentals of inspection, covering the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures (SSOP). Customized HACCP training is then

provided, based on the types of products, raw, ready-to-eat, or shelf stable, being produced at the establishments where inspectors are assigned. More than 1,500 FSIS employees will receive FSRE training in 2004, with an additional 1,000 slated to complete this customized job training regime in 2005. Also in 2003 and 2004 over 200 Consumer Safety Officers, Public Health Veterinarians, and Compliance Officers received Enforcement Investigative and Analysis training. This training focuses on enacting and documenting administrative enforcement action in cases involving violations of food safety requirements.

In August 2003, FSIS announced that employee training would be made more accessible through the establishment of five new regional training sites: Atlanta, Dallas, Philadelphia, Des Moines, and Boulder. Towards this end, FSIS has recently assigned public health training coordinators to the Des Moines, Philadelphia, Dallas, and Atlanta training centers to move training closer to employee worksites and enable us to reach more of our workforce.

During 2004, FSIS trained 140 frontline supervisors in supervision and management of the verification of food safety systems. Also, FSIS has begun to train all new entry-level slaughter establishment inspectors and PHVs in technical, regulatory, and public health methods. The plan is to train 1,200 employees in 2005. FSIS is planning to expand the types of training in the future to meet evolving agency needs and challenges. Also in 2004, FSIS has implemented a

"This Administration remains committed to improving our meat inspection systems. Training for inspectors is an important part of our efforts to ensure that all our systems effectively protect the public health." Agriculture Secretary Ann M. Veneman.

sophisticated food security awareness training for employees. This training has been provided to 4,000 agency employees. This comprehensive two-year training and education effort is designed to ensure that every FSIS employee fully understands his or her role in preventing or responding to an attack on the food supply.

For the 2005 fiscal year, FSIS has requested over a 50-percent increase in the FSIS training budget. These funds are essential so that FSIS can continue to provide vital scientific and technical training to its workforce to protect public health. New employees will now be required to demonstrate mastery of training in order to be certified to assume inspection duties. Additional funds have also been requested to supplement the training for other current field employees to improve enforcement of Hazard Analysis and Critical Control Point/Pathogen Reduction regulations and food safety sampling. The additional funding will also be used to expand the agency's regional training capabilities to reach the workforce with training to address emerging issues.

Food Security

In August 2002, FSIS created the Office of Food Security and Emergency Preparedness (FSIS-OFSEP), which assumed the responsibilities of F-BAT to serve as the centralized office within the agency on food security issues. FSIS-OFSEP is charged with developing the agency's infrastructure and capacity to prevent, prepare for, and respond to actual or suspected deliberate and unintentional, but major, events that threaten the U.S. food supply. FSIS-OFSEP is the lead coordinator and primary point of contact on all food security activities within FSIS and USDA. FSIS' homeland security activities have focused on the following:

In November 2003, FSIS issued the booklet *Food Safety and Food Security: What Consumers Need to Know* at the American Public Health Association's annual convention, one of the largest gatherings of public health officials in the world. In addition, USA Today featured a news story on the importance of the information found in this booklet. These consumer guidelines, available in English and Spanish, offer comprehensive and practical information about safe food handling practices, foodborne illness, keeping foods safe during an emergency, and how to report suspected instances of food tampering.

To ensure the safety of imported products from intentional contamination, since March 2003, FSIS has trained and deployed 20 new Import Surveillance Liaison Inspectors (ISLIs) to augment the efforts of traditional FSIS inspectors assigned to 146 Import Houses around the country. ISLIs conduct

additional surveillance activities at each import facility and at locations outside the facilities where imported product may enter or be stored. They also work to improve coordination with other agencies, such as APHIS and the Departments of Homeland Security and Health and Human Services, which share the responsibility of ensuring the safety of imported food products.

FSIS has also made important security progress on the scientific front. FSIS laboratories have expanded their capability to test for non-traditional microbial, chemical, and radiological threat agents. Construction on a Biosecurity, Level-3 laboratory was completed and the laboratory opened in April 2004. The Biosecurity, Level-3 Laboratory will enable FSIS to conduct analyses on a larger range of potential bioterrorism agents.

The agency also has played a lead role in the development of the Food Emergency Response Network (FERN). Working in collaboration with the Food and Drug

Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), the Department of Energy (DOE), and the States, this network integrates the Nation's laboratory infrastructure and surge capacity at the local, State, and Federal levels. Currently, over 60 laboratories (including public health and veterinary diagnostic laboratories) representing 27 States and 5 Federal agencies have agreed to participate in FERN. The network's primary focus is on method validation, research, training programs, proficiency programs, surveillance, response and surge capacity, and communication in preparation for and response to a potential attack on the food supply. By providing a greater capability to test for biological, chemical, and radiological agents in food, FERN will provide the Nation with a strong scientific infrastructure to protect the food supply. The FERN Steering Committee is also working to establish five Regional Coordination Centers that will serve as the primary points of contact for laboratories in the region. Two of the FERN Regional Coordination Centers are already in operation.

FSIS also plays a key role in the Electronic Laboratory Exchange Network (eLEXNET), a pilot Web-based data exchange system. eLEXNET is currently comprised of 100 participating labs on the Federal, State, and local levels. eLEXNET feeds into FERN and is used as one of their data-capturing mechanisms. eLEXNET can also act as a data-capturing mechanism, and is building the capability to handle sensitive food analyses.



FSIS has signed an agreement with the Army facility at Aberdeen-Edgewood in Maryland under which Aberdeen will accept and analyze high-risk samples for the presence of a variety of biological agents when necessary. Similarly, FSIS signed a Memorandum of Understanding with FDA on January 22, 2004, whereby HHS-FDA will test meat, poultry, and egg products for very low levels of radiological contamination, as necessary.

Finally, to ensure that laboratories as well other offices are secure, the agency hired a Physical Security Specialist in June 2003 to assess the security of FSIS sites and develop internal policies to enhance security of the Agency's personnel and property.

Strengthening Oversight of Recalls

Product recalls are conducted by establishments, either on their own initiative, or as a result of a recommendation made by FSIS. This occurs when there is reason to believe that product that is adulterated or misbranded has entered commerce, or when it has been linked to a foodborne illness outbreak.

In order to improve the effectiveness of product recalls, FSIS issued revised Directive 8080.1, "Recall of Meat and Poultry Products." The changes to the directive are designed to enhance the instructions and guidance to agency personnel responsible for verifying that activities necessary to conduct a recall are performed quickly and efficiently. The agency is also increasing the number of effective-

ness checks that it carries out during Class I recalls (those posing the greatest potential adverse health consequences). Effectiveness checks are designed to ensure that proper notification has been given from the supplier to all consumers, including retail establishments, and that product that is retrieved is accounted for and properly disposed of. The revised directive includes timeframes for reporting verification activities within FSIS and includes provisions for locating products at point of sale.

In an effort to enhance the effectiveness and expediency of the recovery of products involved in a recall, FSIS is exploring possibilities for providing additional information to the public about the distribution of the recalled product. The agency is considering whether additional information can be provided while still preventing the disclosure of proprietary information and preserving the confidential nature of the establishment's business information

Modernization of Enforcement Activities

In order to modernize the agency's enforcement activities, FSIS created the Office of Program Evaluation, Enforcement, and Review (OPEER). This office consists of staffs and divisions previously scattered throughout the agency. These were merged to enhance the agency's evaluation, review, assessment, investigation, enforcement, and audit capacity to thus improve food safety, food security, management effectiveness, efficiency, and decision-making at the Administrator's level.

OPEER is responsible for managing and directing investigations, case development, and documentation of violations of FSIS' laws and regulations. It (1) provides guidance and direction relating to transportation, storage, distribution, and marketing of food products in commerce; (2) monitors State compliance and enforcement programs; (3) monitors and controls regulated products in commerce; and (4) works with OIG and other regulatory and law enforcement authorities in investigations of violations of laws and regulations.

OPEER's Enforcement and Inspection Officers can more accurately and consistently identify and document violations through the use of the recently developed Administrative Enforcement Report, which establishes methodologies and protocols that enhance inspection/enforcement activities. A new internal audit process has been put in place as a proactive measure to identify and review any existing or anticipate any possible future problems that could result from corrective enforcement action. This audit process provides the necessary checks and balances to ensure that enforcement procedures are applied more consistently at the processing level.

OPEER is also conducting independent monitoring in commerce activities of the new BSE surveillance program and food security surveillance of products in distribution. In sum, OPEER' role in examining agency problems and issues, and work with agency leadership in developing policy changes and improvements is both critical and profound. Future work will

include numerous audits, investigations, evaluations or reviews of many key policies and programs.

Strengthening State Reviews

Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), the United States Department of Agriculture (USDA)/FSIS has clear responsibility for setting a national standard for meat and poultry inspection. Under a cooperative agreement with FSIS, States may operate their own programs if they meet and enforce requirements at least equal to those of the Federal program. States may enter into a cooperative agreement for meat inspection, poultry inspection, or both meat and poultry inspection. FSIS is required to monitor State programs and to assume direct responsibility at State plants when a State fails to develop or effectively enforce inspection requirements that are "at least equal to" Federal requirements. To date, 28 States have State programs that operate under a cooperative agreement with FSIS.

Due to heightened security concerns after September 11, 2001, increased agency emphasis on review of all FSIS programs and activities, and the 2002 Farm Bill, FSIS began comprehensive reviews of State meat and poultry inspection programs. In 2003, the agency undertook a series of actions to update and strengthen its policies and procedures for reviewing State meat and poultry inspection (MPI) programs.

The new comprehensive State review process has two parts. First,

each State performed a self-assessment that was submitted to FSIS for review. Second, on-site visits began last fall to determine whether the States are maintaining "at least equal to" programs. FSIS randomly selected four State programs - Kansas, Mississippi, Missouri, and Wisconsin -for on-site reviews. Multi-disciplinary review teams conducted on-site verification reviews in State offices, laboratories, and a sample of establishments. All 28 State programs will eventually have an on-site verification review.

Best Practices for Animal Production

In consultation with producers, researchers, and other stakeholders, FSIS has recently developed guidance which suggests management practices for animal production geared to reducing pathogen loads before slaughter.

Last September, the agency arranged a public symposium to discuss ways to significantly reduce the levels of *E. coli* O157:H7 in live animals before slaughter. The dialogue that was generated from that meeting was very beneficial toward our development of guidelines outlining best management practices at the pre-harvest stage.

Preventing the spread of *E. coli* O157:H7 and other pathogens on the farm is vital to increasing food safety and protecting public health. There are several promising avenues of research including: antibiotics and probiotics, vaccines, sodium chlorate and bacteriophages. FSIS is closely following research development and will encourage

the use of interventions as they are approved.

Producers can take several steps to improve public health through the adoption of on-farm best practices that focus on reducing pathogens and fecal coliforms in feed and water and ensuring the proper handling of manure. Feedlot best practices set up multiple barriers for enteric pathogens by providing safe feed, clean water, and proper manure disposal, thus helping to reduce pathogen loads pre-harvest and reducing the prevalence of *E. coli* O157:H7 in cattle.

FSIS will conduct an aggressive outreach effort to distribute these guidelines to producers in the coming months.

International Food Safety

Food safety and security do not stop at national borders. With the global food supply, countries are interdependent. The way food is traded has a tremendous impact on the health of populations. Increasing international trade has meant that a greater variety of foods are available to the world's population. However, this expansion in food distribution also means that a greater probability exists for unsafe food to reach a large population.

The importance of international food safety led to the creation within the Food Safety and Inspection Service of the Office of International Affairs, which reports directly to the administrator of the Agency. This office brings together all of the agency's activities related to imports, exports, multi-lateral initiatives, and the Codex Alimentarius

Commission. This office is implementing the agency's increased emphasis on international food safety in a number of ways:

First, harmonizing international food safety standards to the extent possible is an important way to improve food safety globally, particularly in developing countries that need assistance in enhancing the quality of their food safety systems. Thus, the United States is very active in the Codex Alimentarius Commission, which is the major international mechanism for developing international food safety standards. The office of the U.S. Codex Manager resides within FSIS, and reports to both the Agency Administrator and the Under Secretary for Food Safety. The latter chairs an interagency committee that develops U.S. policies in food safety, which are presented at Codex meetings. FSIS encourages groups representing industry and consumers to become more involved in Codex, and the agency is engaged in an aggressive outreach program to encourage and assist other countries in participating effectively in the Codex Alimentarius Commission activities.

Another way FSIS ensures the safety of foods traded globally is through the agency's import inspection system. FSIS has jurisdiction over meat, poultry, and processed eggs products, and FDA has jurisdiction over all other foods. However, there are differences in the import inspection requirements demanded by FSIS compared with those required by FDA.

FDA's inspection requirements are company specific, and the agency relies on point-of-entry inspections for all products that are under its jurisdiction. By contrast, instead of interacting directly with individual companies, FSIS deals with the central competent authority within a country before accepting meat or poultry products from that country for sale in U.S. commerce.

FSIS uses a multi-step process to determine whether another country's food regulatory system is equivalent to U.S. standards and the country is eligible to export to the United States. First, the country's laws regarding food safety and its sanitary measures are examined. Second, a multidisciplinary team of FSIS food safety experts visits the exporting country to conduct an on-site audit to verify that the country has satisfactorily implemented all laws, regulations, and other requirements. In addition, the FSIS OPEER office conducts an independent review of these findings.

FSIS does not conduct food inspections in other countries, nor does the agency certify individual foreign establishments for export to the United States. After it has been determined that a country has an equivalent food regulatory system, FSIS relies on that system to carry out daily inspection.

On-site food regulatory system audits are conducted at least annually in each country that exports meat or poultry to the United States. Finally, FSIS has continuous port-of-entry reinspection of products shipped from exporting countries at 146 Import Houses across the country. These reinspections

provide verification that the exporting country's inspection system is functioning well.

FSIS also plays a critical role in ensuring food safety is a key aspect of global trade negotiations and that international science-based standards enhance global public health. In 2003, the Chile Free Trade Agreement (FTA) was signed, and critical decisions were also reached on the Central American Free Trade Agreement (CAFTA), which comprises the countries of Costa Rica, Nicaragua, Honduras, El Salvador, and the Dominican Republic. The Chile FTA included the acceptance by Chile of the systems recognition approach explained above. This approach was advanced by the U.S. trade negotiators and considered crucial by U.S. producers and exporters to realize potential market access gains.

USDA recently entered into a Memorandum of Understanding (MOU) with the Pan American Health Organization to establish ways to improve the safety of meat and poultry products that are traded among the nations of the Western Hemisphere. USDA and PAHO currently collaborate on several projects through strategic alliances to increase and improve food safety, animal health and trade. The MOU is effective immediately and will be in place for the next three years.

Food Handler Education and Outreach

FSIS consumer education programs are modeled on the marketing concept of "integrated marketing" which has three components, each of which supports the other:

- mass media--reaching out to the broad public,
- cluster targeting--utilizing demographic, geographic, and socio-demographic information to target communications to segmented audiences, and
- one-on-one interactions, especially through the USDA's

Food Safety Mobile, expanding outreach programs to include new services and partnerships for minorities and underserved populations both in the U.S. and abroad.

Each component of the integrated marketing program is developed based on risk research, delivered utilizing social marketing concepts, and assessed through evaluative research. Ongoing nationwide surveys and consumer focus group studies are used to evaluate and ensure the continuing effectiveness

of the initiative and to continue to track the documented changes in consumer behavior.

One such initiative currently planned is a targeted thermometer education campaign in the State of Michigan during August 2004. FSIS is working with the National Food Safety and Toxicology Center from Michigan State University, along with local partners, to host events in 3 cities: Ann Arbor, Lansing, and Grand Rapids. The goal is to increase the use of food thermometers and prevent foodborne illness.

The initiative will use social marketing principles to promote positive behavior change. The target audience will be a selection of parents of young children under age 10, chosen as most likely to change behavior. Before-and-after testing will be conducted by Michigan State University and an overall evaluation will be conducted in collaboration with USDA to assess the effectiveness of this effort. This pilot will be a role model for other States and may serve as the basis for a possible national launch of this initiative in 2005.

FSIS is committed to communicating with all food handlers, especially those who serve others in large-scale food operations, or are personally at-risk for foodborne illness. The agency has made great strides in reaching out to citizens who may not speak English. Food safety publications for both industry and consumers have been translated into several languages including Spanish, Korean and Mandarin Chinese. The agency utilizes national television, cable networks, educa-

tional television, radio, magazines, newspapers, and Web sites to enhance public education efforts.

In January of 2004, Agriculture Secretary Ann M. Veneman announced an aggressive program to enhance USDA's electronic government capabilities as part of President Bush's Management Agenda. The agency responded to the challenge by expanding its reach to consumers through cyberspace. In April of 2004, FSIS launched its newly designed, customer-focused Web site to help make finding information about food safety easier and faster by providing continuous, uninterrupted global capabilities around the clock. The redesigned FSIS Web site was the first of the Department's agencies to debut as part of the Secretary's initiative.

The revamped Web site provides the latest information about food safety with an innovative twist. Consumers can communicate with "Karen," the FSIS virtual hotline representative. "Karen" can answer

questions about safely storing, preparing, and handling meat, poultry, and egg products. "Karen" instantly can respond to questions originating from anywhere in the world. (Of course, consumers can also still call the USDA Meat and Poultry Hotline, 1-888-MPHotline (1-888-674-6854) with questions.)

Ensuring that meat, poultry and egg processing plants understand the agency's directives and regulations is a key aspect of the agency's outreach program. The agency has recently initiated a series of teaching workshops designed to provide owners and operators of plants with detailed information about new directives as well as updated procedures inspectors will follow in verifying plant compliance in several areas. Workshops have been held across the country on such topics as *Listeria monocytogenes*, BSE, and *E. coli* O157:H7. Over 1000 attendees have benefited from these interactive sessions. The information from these workshops is available upon request, in both English and Spanish.



SECTION IV:
Achieving the Next
Level of Food Safety

The first challenge is the need to anticipate/predict risk through enhanced data integration

FSIS is engaged in developing innovative ways to anticipate hazards, so that it can act to ensure that those hazards do not manifest themselves as public health problems. One significant way in which this can be accomplished is by thoroughly analyzing data obtained from FSIS' regulatory sampling, as well as other sources of data, so as to discern trends and identify connections between persistence, prevalence and other factors, such as practices employed at plants, seasonal variations, and size of establishment.

Currently, the agency is examining its regulatory data to identify conditions that consistently have presaged the development of significant problems. A goal is to have inspection personnel utilize these data on a regular basis so that they can make decisions and inform the establishment in order to have them take corrective action that may prevent a problem. Including data collected by the establishment would add robustness to the information and would improve the quality and validity of conclusions made. This would contribute to enhanced actions that could truly prevent problems.

A second assessment tool that the agency is developing to help its inspection personnel anticipate problems is a hazards guide. The agency has a contract with a vendor for the development of this guide, which will assist inspection personnel in delineating the hazards associated with a particu-

"Food safety is too important to be left to guess work or luck; we must be prepared to identify and meet challenges head on. We still have room for improvement in lowering foodborne illness, and it takes all parties, from all backgrounds in the farm-to-table chain to take responsibility and work together to ensure that our food supply continues to be the safest in the world." Dr. Elsa Murano, Under Secretary for Food Safety.

lar process (rather than a product), and to assess whether the establishment is addressing that hazard. The agency intends to ensure that relevant data such as the results of the agency's investigations of recent outbreaks, and the agency's conclusions about the products involved, is included, in addition to other data. The guide will help inspection personnel divide an establishment's operation into its component processes and to analyze the establishment's approach to each process. The ability to do so should enable inspection personnel to more effectively evaluate the establishment's hazard analysis. It will give them the means with which to assess whether the establishment is correctly identifying the hazards that may occur in its operation and is addressing those that are reasonably likely to occur.

A third assessment tool that the agency is considering is to establish

new performance standards. These standards could be developed based on baseline studies which the agency is scheduled to begin this summer, or, as the National Advisory Committee on Microbiological Criteria for Food (NACMCF) has stated, existing agency data. One approach is to establish performance standards that are informal, rather than regulatory standards like the *Salmonella* standards that the agency adopted in 1996. As guidelines, the agency could use the performance standards as benchmarks to determine whether establishments are appropriately controlling pathogens in their operations. While there would not be formal regulatory consequences for failures, a failure would provide an indication that the agency needs to take a closer look at the establishment through in-depth verification reviews, which could result in regulatory action. Because the performance standards would only be guidelines, the agency would be free to change them, either in response to a new baseline or other newly available data, or to modify the point at which the agency would consider a food safety assessment warranted, without having to conduct a lengthy process. This would add flexibility and speed to the agency's ability to change the guidelines according to new data, which would provide a much more scientifically accurate trigger for conducting in-depth verification reviews. FSIS will continue to explore this and other approaches to performance standards.

FSIS has innovative initiatives underway to provide it with tools that will enable it to anticipate risk.

However, ensuring the availability of data to FSIS from industry, academia, States, consumers, and foreign countries will be necessary if the agency is to maintain the currency of these tools.

One way that this can be accomplished is through the establishment of a third-party data repository. This could be done through a contract with an academic institution in such a way as to protect the integrity of the data, while providing the confidentiality to industry that would be required in order to ensure that no consequences would be derived from sharing plant data with FSIS.

FSIS recently asked the National Advisory Committee on Meat and Poultry Inspection (NACMPI) how the agency can ensure ready access to data from all relevant sources, including consumer groups, the States, and foreign countries. Several suggestions emerged from the group's deliberations and recommendations:

- The Committee suggested that FSIS provide the public with information on how it would like to receive data that is voluntarily submitted. For example, given the fact that data could be used against a company that is the source of the data, the agency should define the circumstances in which it would consider anonymous data useful. The agency should address whether the removal of identifiers would be acceptable, and whether it would accept aggregate data.
- The Advisory Committee suggested a public meeting to discuss the ground rules for agency access to data. The Advi-

sory Committee also suggested that public meetings would be useful on specific matters on which FSIS needs data.

- The Committee also suggested that the agency make greater use of the correlations that were done in-plant by the Technical Service Center. The Advisory Committee stated that the results of these correlations might point to conditions that were predictive of more significant problems.
- The Advisory Committee suggested that FSIS conduct event analyses of significant problems. The analyses would explore why the event occurred, why it occurred in the particular establishment involved, and what could have been done to prevent it.

The agency is currently examining these and other options, in order to determine the course of action that will best enable it to anticipate risk, and thereby protect public health.

The second challenge is the need for improved application of risk into regulatory and enforcement activities. Food safety problems need to be documented as they occur, so that conditions may be analyzed and corrected as appropriate. A better understanding of the prevalence and types of food safety failures could allow better assessment of how to best address them. Data regarding the causes of food safety violations, either within a specific establishment, or within a class of establishments, can be utilized in order to better focus our attention where the risks are greatest. In addition, it can provide us a tool to determine enforcement trends by

district and by circuit, which supervisors can use to determine whether enforcement actions are being consistently applied.

FSIS has developed, and is beginning to field-test, a "real-time" measure of how well establishments control the biological, chemical, and physical hazards inherent in their operations. This measure, the Hazard Control Coefficient (HCC), uses both in-plant and laboratory inspection and verification findings from an establishment during the past 6 months to quantify the level of compliance with regulatory requirements. HCCs are computed so they range from 0 to 20, with lower HCCs indicating fewer deviations from regulatory requirements. HCCs are updated monthly using the most recent 6 months of agency data, and are used as a management tool.

Thus, HCCs could be assigned to each meat, poultry, and egg processing plant in the U.S., allowing FSIS to divide them into groups, according to how well each is complying with agency regulations.

HCCs are still in a developmental phase, and so a field-test has begun that involves monthly transmission of the HCCs to District Inspection Coordinators for the establishments in their own districts. These transmittals to a given district office commence only after one or more headquarters personnel, with thorough conceptual and computational knowledge of the HCC, visit that office to explain what HCCs are, how they are computed, and how they can be properly interpreted. The primary purpose of the field-test is to obtain input

from the district office personnel on how HCCs might be improved so they can be a more useful management tool. How HCCs are actually computed, however, will not be revised without due input from senior agency managers.

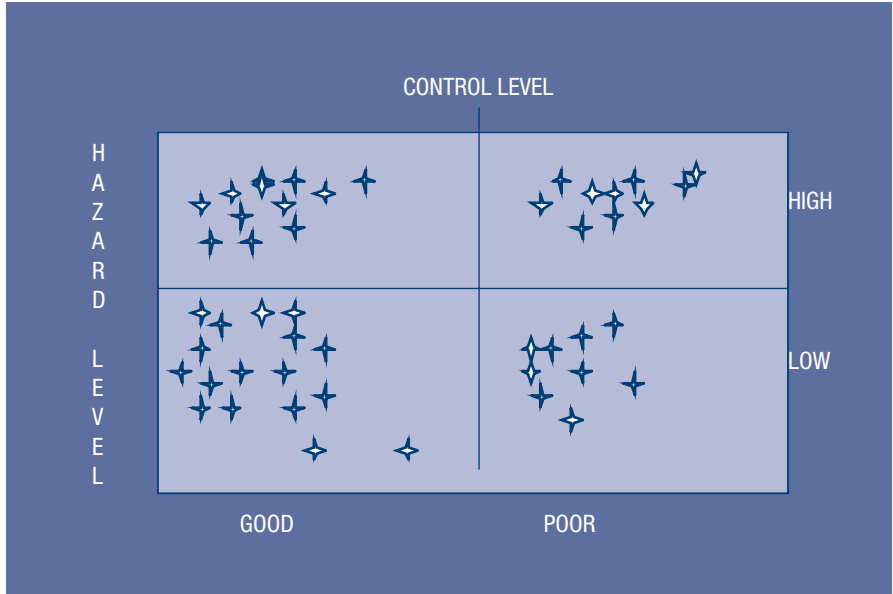
HCCs have the potential to help the agency better focus its activities across this country's more than 6,000 meat and poultry establishments based on how well they control hazards, thereby improving food safety and public health protection.

In conjunction with HCCs, the agency has developed the concept of a Hazard Coefficient (HC). HCs are measures of the inherent hazards in federally inspected meat and poultry establishments, based on the species of animal slaughtered or processed in the establishment, the types of products that the establishment produces, and the establishment's production volume. HCs were recently used to help prioritize E.coli O157:H7 reassessment efforts.

Just like HCCs, HCs could be assigned to each meat, poultry, and egg processing plant in the U.S. Combining HCC and HC data would enable the agency to determine which establishments producing low-versus high-risk products are best able to control hazards. This structure could serve to develop a strategy by which plants in need of attention would be identified, thereby ensuring better use of agency resources.

Similar to the HCC and HC concepts, the agency is also beginning an effort to develop Food Security Risk Coefficients (FSRCs). FSRCs will be numerical indicators of how well operators of federally inspected meat and poultry establishments protect themselves from the intentional introduction of hazards into their products. FSRCs are designed to indicate the possibility of problems if establishments are not doing a good job. The data for the FSRCs will come from a survey of Inspectors-in-Charge (IICs) to be administered by the agency in the near future. Survey questions

A predictive model to help with resource allocation decisions



will be constructed from a number of sources, including from the FSIS Security Guidelines for Food Processors published in May 2002.

The agency uses in-depth verifications and other food safety assessments to examine an establishment's HACCP system, or some narrower aspect of the establishment's operation, to determine what factors contributed to the food safety problems that have occurred. FSIS is revising the directives on food safety assessments to clarify the purposes behind these investigations and to tailor the assessments so that they are best able to achieve their purposes. For example, FSIS is attempting to develop a methodology specifically designed to find the source of E.coli O157:H7 problems and to provide the basis for enforcement actions that focus specifically on these problems. Moreover, the agency is conducting a review of the numerous assessments that have been conducted to date, in order to determine whether any conclusions or principles can be extracted that may be useful in developing future strategies.

To ensure that food safety problems are appropriately documented when they occur, the agency has and its partners in public health are working to this end through FoodNet.

FoodNet is the Foodborne Diseases Active Surveillance Network. It is a collaborative project of the CDC, FSIS, FDA, and 10 FoodNet sites located in various parts of the U.S. Through laboratory surveillance for infections with certain bacteria and parasites more commonly transmit-

ted by food, and by conducting special studies, FoodNet goals are to determine more precisely the burden of foodborne diseases, monitor foodborne diseases trends, and determine the proportion of foodborne diseases attributable to specific foods.

FoodNet has been successful in the first two goals. In January 2003, FoodNet formed a working group to determine how to identify the proportion of foodborne diseases attributable to specific foods. FSIS has 10 people serving as members of this working group. This project is of particular importance to FSIS, as the agency looks for indicators of the success of HACCP and as it looks to identify areas where improvement may be needed.

So far the working group has examined how outbreak cases contribute to the overall burden of illness, versus sporadic cases, or non-outbreak associated cases. The group has been successful in moving the sites forward in improving the gathering of travel histories for those ill, as foreign travel is a risk factor for some infections and may not be associated with eating foods in this country.

A key project or study for FSIS is the development of mathematical models to arrive at estimates of the attribution of illnesses caused by various food commodities. The first such model will target the contribution to foodborne disease from the various serotypes of *Salmonella*. The study will use a mathematical model that combines the results of surveys of the prevalence of the target pathogens in all of the major classes of commodities. FSIS verifi-

cation testing program data are a key data source for this project. In the model, these data will be linked to this information from food consumption surveys and from public health surveillance that tracks the relative prevalence of the target pathogens in human foodborne disease. Using these data simultaneously will enable estimates of:

1. the relative ability of different pathogens to survive from reservoir to the point of human ingestion,
2. the relative abilities of different pathogens to cause human disease once ingested, and
3. estimates of the contribution of the different food commodities in causing human foodborne disease.

The model, being developed by the University of Minnesota, is almost complete. The FSIS working group members are working diligently to get the FSIS data ready to send to the modeler. A final product is expected in the fall of 2004.

The fourth challenge is improving food safety beyond our borders.

This challenge was not included in the 2003 vision document; however, it is important to note that food safety is an issue of global importance. As such, it needs to be recognized that FSIS' efforts transcend U.S. borders, and paying special attention to this reality can help guide the agency's fulfillment of its vision for food safety. With the proliferation of movement of people, food and agricultural products between countries, the likelihood of food that is produced in one country being consumed on the dinner table in another is

increasing. The acceleration and expansion of this process is evidenced and hastened by the multitude of regional, bilateral and multilateral trade relationships being pursued and established among countries. With this trend FSIS has emerged not only as an established leader in effective food safety standards and regulations for the U.S., but also as the vanguard entity responsible for enhanced food safety on a global scale.

In particular, the nations of the Americas make up a regional community ever more closely entwined in the challenge of ensuring food safety and security for this hemisphere, and beyond. Open and effective exchange of information and education on food safety risks, and on how to control those risks, will play a critical role in improving the food safety and public health of the region.

To address these concerns, FSIS is working to establish a Food Safety Institute of the Americas (FSIA) to bring together the region's resources and serve as a focal point for the exchange of food safety information. The partnership and collaboration among its member institutions and organizations will significantly contribute to a reasoned dialogue about food safety and security issues of concern. Such an organization can also promote the development of science-based international food safety standards. The common language of science will serve to enhance understanding of the policies and procedures within the activities of the Codex Alimentarius Commission. The development of the FSIA and the outreach activities

of Codex can synergize the improvement of public health in all communities in the Americas.

The goal of the FSIA would be to institutionalize and harmonize food safety education, information, and communication throughout the region. The FSIA would carry out major outreach activities to identify, develop, and coordinate educational programs, as well as to promote the development of international science-based food safety standards.

The FSIA is an innovative concept for reaching a broad and diverse audience in the Americas. It can serve to address food safety concerns in the region by establishing and enhancing important networks among regulatory officials; researchers; public health officials; meat, poultry, and egg processors and producers; and animal producers.

"In today's market, we must take a global approach to food safety. That means working with our trading partners to improve the safety of foods worldwide." Under Secretary Dr. Elsa A. Murano

SECTION V:
Conclusion

The implementation and maintenance of the strategies described in this vision paper have led to significant, measurable advances in FSIS' mission to protect public health. These initiatives will provide an essential and important foundation for the future. Not only is it critical for FSIS to continue to refine and enhance

these advances based on its current regulatory authority and available scientific knowledge, it is essential that the agency continue to modernize its inspection system through risk-based approaches and further refine its management agenda in order to have the flexibility to meet ever changing threats to public health.

